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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,511	10/15/2004	Michael R. Emmert-Buck	4239-64816-02	4331

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EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,511	EMMERT-BUCK ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-26,34 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7,9-26,34 and 35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7 and 9-19, drawn to a detection method of analyzing a tissue sample.

Group II, claim(s) 20-26 and 34-35, drawn to a method of screening for disease.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-II do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature shared by the Groups is the method of Group I analyzing a protein or nucleic acid component of a sample.

However, Harlow & Lane (Harlow, E. and Lane, D., Antibodies: A Laboratory Manual (1988) Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY, pages 359, 361-369, 390-401) teach protocols for cell staining, in which a "Direct Cell Target Analysis" (DCTA)

molecule (directly labeled antibody) is contacted with a tissue sample under conditions that allow the antibody portion of the molecule to interact with antigens within the tissue sample (see especially p. 361-362). The DCTA molecules comprise a targeting moiety (antibody) capable of localizing the DCTA to the target antigen in the sample, as well as an active moiety (label) capable of generating a detectable signal, for example a fluorochrome, enzyme, or gold label (see also p. 390). Harlow & Lane further teach activating the active moiety and detecting the signal or product generated, for example by fluorescent or enzyme-based detection (p. 390). In the case of an enzyme active moiety, the enzyme is activated by addition of substrate as secondary reagent and detected by detecting the colored product (see also p. 391 and p. 396-400).

Therefore, the technical feature linking the inventions of Groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

In addition, Group I includes the technical feature of screening disease, which is not a feature of the detection method of Group I. Accordingly, Groups I-II are not linked by the same or a corresponding special technical feature so as to form a single general inventive concept.

Election of Species

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a. **Type of targeting moiety** (elect one of the following):

i. Variable region of an antibody binding domain (see claim 3)

ii. Variable region of a secondary antibody binding domain (see claim 4)

iii. Ligand that specifically binds to a receptor protein (see claim 5)

iv. Nucleic acid molecule (claim 6)

v. Reverse transcriptase molecule (claim 7)

vi. DNA polymerase molecule (see claim 7)

b. **Type of detectable product** (elect one of the following):

i. cDNA transcripts (see claim 7)

ii. DNA transcripts (see claim 7)

iii. Iodinated tryptophan or tyrosine (see claims 12-13)

c. **Type of active moiety** (elect one of the following):

i. Lactoperoxidase (see claims 12-13)

d. **Type of target component in the sample** (elect one of the following):

i. Protein (see claims 5 and 20)

Note: in the event that "protein" is elected, a specific type of protein must also be elected.

(a) Receptor protein (see claim 5)

(b) Hormone (see claim 23)

ii. Nucleic acid (see claims 6)

In the event that Group II is elected, the following species election must also be made (in addition to the species elections listed above).

e. **Type of disease to be screened** (elect one of the following):

i. Neoplasia (see claims 25 and 34-35)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. **The reply must also identify the claims readable on the elected species, including any claims subsequently added**. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above as indicated.
The following claim(s) are generic: claims 1-2, 9-11, 16, and 18 appear to be generic. Claims 3-7, 12-15, 17, 19-26, and 34-35 are subject to species election.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species of **targeting moieties** are different because each represents a distinct molecule that differs with respect to structure, chemical composition, function, and reactive properties; and the various types of targeting moieties would detect different components of the tissue sample. For example, a targeting moiety that is nucleic acid differs from a targeting moiety that is an antibody since nucleic acids are polynucleotides

that bind to other nucleic acids by complementary sequence hybridization, while antibodies are proteins made up of amino acids residues that specifically bind antigens through their complementarity-determining regions. For similar reasons, the types of **targeted component in the sample** that is detected differ because proteins are chemically, functionally, and structurally distinct from nucleic acids. The species of **detectable products** are different because each invokes different assay reagents, method steps, and means of detection. Similarly, in the case of different **diseases** to be screened, each disease would invoke a different biomarker that is detected in the sample, with its own associated assay reagents (e.g. targeting moiety) in order to detect that biomarker.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1641

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